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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,202	07/29/2003	Douglas Pat Cerretti	2861-US-A	3148

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IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/633,202	Applicant(s) CERRETTI, DOUGLAS PAT	
	Examiner William W. Moore	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19, 21-28, and 30 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 21 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse in the Response filed 17 October 2006 of the invention of Group 1 - now comprising claims 17-19, 21 and 30 as claims 13-16, 20 and 29 were cancelled in the reply - is acknowledged. The traversal is on the grounds that a polynucleotide of Group 2 may only encode a polypeptide of Group 1. This is not found persuasive because the different inventions are not disclosed to be used together and require separate searches in the commercial and USPTO nucleic acid sequence or amino acid sequences databases and in the patent and non-patent literature. An additional search burden is an undue search burden. The requirement is still deemed proper and is therefore made FINAL and claims 22-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the requirement for restriction in the Response filed 17 October 2006.

Response to Amendment

Applicant's cancellation of claims 13-16 and 20, introduction of the new claim 30, and amendment of claims 17 and 18 so they depend from the new claim 30, permit claims 17-19, 21 and 30 to avoid the rejections of record of the elected claims herein under the first paragraph of 35 U.S.C. § 112 for lack of an adequate written description and for lack of enablement as to making. Comparison, however, of the subject matter of the new claim 30 to the subject matters of clause (g) of claim 17 and of claim 19, as it is disclosed in the specification, requires the following objection to the claims.

Claim Objections

Claims 17 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, in this

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instance the new claim 30 from which claim 17 has been amended to depend. In particular, the new claim 30, unlike the canceled claim 14, requires that polypeptides "compris[e] the amino acid sequence of amino acids 399 through 502 of SEQ ID NO:2". Yet neither the polypeptide of clause (g) of claim 17 nor the structure of SEQ ID NO:3 of claim 19 – which is described at page 59 of the specification to have the amino acid sequence of the SVPH1-26 polypeptide from "Cys410" to "Arg692 of SEQ ID NO:2" represented in the "amino acids 23-305 of SEQ ID NO:3" - need comprise the amino acid sequence region of SEQ ID NO:2 recited in claim 30. Thus claims 17 and 19 no longer meet the structural limitations of claim 30 from which both ultimately depend. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. To overcome this objection, Applicant may amend claim 30 to substitute the amino acid sequence of clause (g) of claim 17 for the phrase, "amino acids 399 through 502 of SEQ ID NO:2", if such substitution is functionally appropriate or, alternatively, both delete clause (g) from claim 17 and delete claim 19.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-19 and 21 remain rejected, and the new claim 30 is now rejected, for reasons of record under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed in the Response of 17 October 2006 have been fully considered but they are not persuasive. At pages 5-9 of the Response Applicant suggests that, because "SVPH1-26", including the disintegrin domain of claim 30, "is predominantly expressed in testis tissue", a generic "usefulness of an integrin-binding protein, particularly one that is predominantly expressed in a critical tissue" creates an

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anticipat[ion] that use may be made of the disintegrin domain and its integrin binding properties." Applicant asserts that the polypeptides of the claims have a credible utility in pointing to the teaching of Almeida et al., 1995, made of record herewith, that "[t]he observation that fertilin β possesses a disintegrin domain . . . led us to predict that an integrin on the egg plasma membrane could serve as a sperm receptor."

The issue is not that of the presence or absence of a credible utility but whether or not a claimed invention possesses a specific and substantial *in vitro* or *in vivo* utility. It was agreed in the communication mailed 17 April 2006 that the amino acid sequence of SEQ ID NO:2 comprises a disintegrin domain that shares a detectable degree of amino acid sequence identity with disintegrin domains in the prior art. Neither Almeida et al., discussing a polypeptide having a disintegrin domain structurally distinct from the sequence of amino acids from position 399 through position 502 of SEQ ID NO:2, nor the instant specification disclose a specific *in vitro* or *in vivo* utility for the disintegrin domain in SEQ ID NO:2. While the specification proposes, at page 6, the use of the SVPH1-26 disintegrin domain in assays to detect inhibitors of its undisclosed activity, and discusses, at page 9, the resemblance between the amino acid sequence of the SVPH1-26 disintegrin domain and those of other mammalian disintegrin domains, there is no showing that the disintegrin domain from position 399 through position 502 of SEQ ID NO:2 mediates fertilization or any other physiological activity and no teaching of how it might specifically affect any particular physiological activity. "A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The rejection of record is maintained because the specification does not indicate that Applicant knew of a specific utility for the SVPH1-26 disintegrin domain.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.


Claims 17-19 and 21 remain rejected, and the new claim 30 is now rejected, for reasons of record under 35 U.S.C. § 112, first paragraph, for lack of enablement as to use of a claimed invention because, where the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
29 December 2007


NASHAAT T. NASHED, Ph.D.
PRIMARY EXAMINER